K071774

MAQUET

JAN 23 2008

510 (K) Summary [as required by 21 CFR 807.92(c)]

Submitter:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person:	Katrin Schwenkglenks Phone: +49 7478 921-151 Fax: +49 7478 921-400 E-mail: katrin.schwenkglenks@maquet-cp.com
Date Prepared:	June 22, 2007
Device Trade Name:	Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating
Common/Usual name:	Quadrox D Bioline
Classification names:	Oxygenator, cardiopulmonary bypass Heat Exchanger, cardiopulmonary bypass
Predicate Device:	Jostra Quadrox D Safeline Hollow Fiber Membrane Oxygenator (K061628)

Device Description:

The Quadrox D Bioline is a sterile and non-pyrogenic device, for single use only and is not to be re-sterilized by the user.

In open heart surgery it is used in combination with the heart-lung machine for the oxygenation of blood and removal of carbon dioxide. The Quadrox D Bioline is therefore a component in the extracorporeal perfusion circulation system, for oxygenation of blood and removal of carbon dioxide. The utilization period of this device is restricted to six hours.

The Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating is exactly the same oxygenator as the Quadrox D Safeline (K061628) in design, materials, sterilization process and intended use, but the coating is different. The new device comes with a Bioline coating, the already cleared device comes with the Safeline Coating.

With this diffusive membrane the gas exchange takes place by diffusion through the membrane wall. This membrane has no pores, therefore a passover of air bubbles or plasma leakage is not possible.

The performance data of the Quadrox D Safeline are comparable with the performance data of the Quadrox Safeline Oxygenator.

The Quadrox D Bioline may be marketed both as single product and pre-mounted with the venous hardshell cardiotomy reservoir (K003551, K982136), equivalent to the Jostra Quadrox D Safeline (K061628).

Indications for Use:

The Membrane Oxygenator Jostra Quadrox D is used for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours.
The application and use of the oxygenator is the sole responsibility of the attending physician.

Statement of Technical Comparison:

The Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating has the same intended use, design, principals of operation, and performance as the Jostra Quadrox D Safeline Oxygenator. Only difference is that the new device comes with a Bioline coating, the already cleared device comes with the Safeline Coating.

Non-clinical Testing:

The Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating has been tested to and met the requirements of ISO 10993-1 Biologic Evaluation of Medical Devices as well as the requirements of ISO 7199: 1996 "Cardiovascular implants and artificial organs – blood gas exchangers (oxygenators).

Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was executed to demonstrate that the Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating described in this submission is substantially equivalent to the Jostra Quadrox D Safeline Diffusion Membrane Oxygenator.

The following areas have been tested:

- Integrity
- Performance
- Stability of the Coating
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating is substantially equivalent to the named predicate device which holds currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2008

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen, Germany

Re: K071774
Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating
Regulation Number: 21 CFR 870.43500
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: January 14, 2008
Received: January 18, 2008

Dear Ms. Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071774

Device Name: Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating _____

Indications for Use:

The Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating is used for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours.
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Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna R. Uchner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071774

(Posted November 13, 2003)

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